

NIH Implementation of Office for Human Research Protections (OHRP) Guidance on Research Involving Coded Private Information or Biological Specimens

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Key Dates

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On August 10, 2004, the Office for Human Research Protections (OHRP), Department of Health and Human Services, issued Guidance on Research Involving Coded Private Information or Biological Specimens, available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>. The OHRP guidance, which was addressed to Institutional Review Boards (IRBs), investigators, and funding agencies, affects the way the NIH and applicant institutions process applications involving coded private information or human biological specimens. This Notice explains changes that NIH has made to grant application and contract proposal instructions to reflect the OHRP Guidance. This Notice is a follow-up to NOT-OD-04-069 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-069.html>), published September 17, 2004.

To assist institutions and investigators in preparing grant applications that involve coded private information and human biological specimens, the NIH has added definitions and clarifications relevant to the OHRP Guidance to the PHS 398 (rev. 9/2004) instructions (<http://grants.nih.gov/grants/forms.htm>).

These additions and changes appear in all three parts of the PHS 398; however, the majority are in "Part II: Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan."

Please note that the information in the PHS 398 grant application is to be used by investigators and peer reviewers to help determine the applicability of the OHRP Guidance to the proposed research. The information provided does not redefine or reinterpret OHRP's Guidance. Should questions about the applicability of the OHRP Guidance arise, NIH will consult with OHRP before making a determination.

All new and competing continuation grant applications and non-competing grant progress reports (Type 5) involving coded private information or biological specimens submitted to NIH on or after January 10, 2005 should follow the revised instructions outlined in the PHS 398 . Although use of the 9/2004 version of the PHS 398 (<http://grants.nih.gov/grants/funding/phs398/phs398.html>) is not mandatory until May 10, 2005, this version includes detailed instructions to help applicants to apply the OHRP guidance. To minimize confusion in application preparation, applicants are urged to use this new version for applications impacted by this guidance.

When submitting the PHS 2590 (Non-Competing Grant Progress Report), if there are any changes regarding Human Subjects, check the "Change" box on Form Page 5, and follow the instructions under the Progress Report Summary, d. Plans, which direct you to follow the instructions in the "Human Subjects" section of the PHS 398. If changes occur to the Involvement of Human Subjects as a result of the OHRP Guidance (see instructions outlined in the PHS 398), please indicate so in the progress report summary.

For investigators and institutions submitting contract proposals in response to NIH Requests for Proposals (RFP), information presented in the relevant RFP and on the OER website should be used in the implementation of the OHRP Guidance.

NOTE: If you have downloaded and/or printed a copy of the PHS 398 (9/2004) before this revised version of the PHS 398 was available, you should print or download this revised version (<http://grants.nih.gov/grants/forms.htm>) and discard the previous copy.

Inquiries

If you have questions about the OHRP Guidance, please contact OHRP by email at ohrp@osophs.dhhs.gov.

If you have questions about NIH implementation, please contact the Office of Extramural Programs, Office of Extramural Research, Office of the Director, NIH, by email at OEPMailbox@mail.nih.gov.

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